Liza M. Walsh
Christine I. Gannon
Eleonore Ofosu-Antwi
CONNELL FOLEY LLP
One Newark Center
1085 Raymond Boulevard, 19th Floor
Newark, New Jersey 07102
(973) 757-1100

OF COUNSEL

David T. Pritikin
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, Illinois 60603
(312) 853-7000

Attorneys for Immunex Corporation and Amgen Manufacturing, Limited

David De Lorenzi
Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4500

OF COUNSEL

David I. Berl
Thomas S. Fletcher
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, D.C. 20005
(202) 434-5000

Attorneys for Hoffmann-La Roche Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IMMUNEX CORPORATION; AMGEN MANUFACTURING, LIMITED; and HOFFMANN-LA ROCHE INC.;	Civil Action No. _____
Plaintiffs,	**COMPLAINT & DEMAND FOR JURY**
v.	
SANDOZ INC.; SANDOZ INTERNATIONAL GMBH; SANDOZ GMBH;	***Confidential - Filed Under Seal***
Defendants.	

COMPLAINT

Plaintiffs Immunex Corporation; Amgen Manufacturing, Limited; and Hoffmann-La Roche Inc., by and through their undersigned attorneys, for their Complaint against Defendants

Sandoz Inc.; Sandoz International GmbH; and Sandoz GmbH (collectively, "Defendants") allege as follows:

I. THE PARTIES

A. Plaintiffs

1. Immunex Corporation ("Immunex") is a corporation organized and existing under the laws of the State of Washington with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen Inc. acquired Immunex in July 2002, and Immunex became a wholly-owned subsidiary of Amgen Inc.

2. Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of the Territory of Bermuda, with its principal place of business at Road 31 km 24.6, Juncos, Puerto Rico 00777. AML is a wholly-owned subsidiary of Amgen Inc.

3. Hoffmann-La Roche Inc. ("Roche") is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424.

B. Defendants

4. On information and belief, Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, with its principal place of business at 100 College Road West, Princeton, New Jersey 08540. Upon information and belief, acting in concert with each of the other Defendants, Sandoz Inc. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the State of New Jersey and throughout the United States. Upon information and belief, Sandoz Inc. is also the United States agent for Sandoz International GmbH and Sandoz GmbH for purposes including, but not limited to, filing regulatory submissions to and corresponding with the Food and Drug Administration ("FDA").

5. Upon information and belief, Sandoz International GmbH is a corporation existing under the laws of the Federal Republic of Germany with its principal place of business at Industriestraße 25, 83607 Holzkirchen, Germany. Upon information and belief, acting in concert with each of the other Defendants, Sandoz International GmbH is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the State of New Jersey and throughout the United States.

6. Upon information and belief, Sandoz GmbH is a corporation existing under the laws of the Republic of Austria with its principal place of business at Biochemiestraße 10, 6250 Kundl, Austria. Upon information and belief, acting in concert with each of the other Defendants, Sandoz GmbH is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the State of New Jersey and throughout the United States.

7. Upon information and belief, Sandoz GmbH operates as a subsidiary of Sandoz International GmbH.

8. Upon information and belief, Defendants collaborate to develop, manufacture, seek regulatory approval for, import, market, distribute, and sell biopharmaceutical products (including products intended to be sold as biosimilar versions of successful biopharmaceutical products developed by others) in the State of New Jersey and throughout the United States.

II. NATURE OF THE ACTION

9. This is an action for patent infringement arising under 35 U.S.C. § 271, including § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("the BPCIA"). This action involves patents that cover etanercept (the active ingredient of the biologic drug product, ENBREL®), its method of manufacture, certain materials used in its manufacture, and certain therapeutic uses of etanercept. Immunex and AML

(collectively, "Immunex/AML") and Roche bring this suit to enjoin Defendants from infringing their patents and to recover any damages resulting from Defendants' infringement.

10. The asserted patents are United States Patent Nos. 8,063,182 ("the '182 patent"), 8,163,522 ("the '522 patent"), 7,915,225 ("the '225 patent"), 8,119,605 ("the '605 patent"), and 8,722,631 ("the '631 patent") (collectively, "the patents-in-suit").

11. Roche is the owner of the '182 and '522 patents. Immunex is the exclusive licensee of all commercial rights in the '182 and '522 patents, including all rights to sell ENBREL®.

12. Immunex is the owner of the '225, '605, and '631 patents.

13. Immunex has granted AML an exclusive license (or, with respect to the '182 and '522 patents, an exclusive sublicense) to the asserted patents.

14. On September 29, 2015, the FDA accepted Defendants' abbreviated Biologics License Application ("aBLA") pursuant to the BPCIA, specifically 42 U.S.C. § 262(k) (also known as § 351(k) of the Public Health Service Act ("PHSA")), seeking authorization from the FDA to market a biosimilar version of Immunex's ENBREL® (etanercept) product.

15. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. The abbreviated pathway (also known as "the (k) pathway") allows a biosimilar applicant (here Sandoz Inc.) to rely on the prior licensure and approval status of the innovative biological product (here ENBREL®) that the biosimilar purports to copy. Immunex is the sponsor of the reference product, ENBREL®, which is approved by the FDA for a number of different indications (*i.e.*, therapeutic uses).

16. Defendants committed an act of infringement under 35 U.S.C. § 271(e)(2)(C) when they caused Sandoz Inc. to submit Defendants' aBLA seeking FDA approval to

commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Defendants' etanercept product prior to the expiration of the asserted patents.

17. If the FDA approves Defendants' aBLA, Defendants will also infringe one or more claims of each of the patents-in-suit, under 35 U.S.C. § 271(a), (b), or (g), should they engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Defendants' etanercept product.

III. JURISDICTION AND VENUE

A. Subject-matter Jurisdiction

18. This Court has subject-matter jurisdiction over Immunex/AML and Roche's patent infringement claims under 28 U.S.C. §§ 1331, 1338(a), and 2201(a).

B. Sandoz Inc.

19. This Court has personal jurisdiction over Sandoz Inc. by virtue of the fact that, on information and belief, Sandoz Inc.'s principal place of business is in the District of New Jersey.

20. Sandoz Inc., Sandoz International GmbH, and Sandoz GmbH hold themselves out as a unitary entity and have represented to the public that their activities are directed, controlled, and carried out as a single entity.

21. For example, during prior litigation brought by Sandoz Inc. concerning the '182 and '522 patents, *see Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274 (Fed. Cir. 2014), Sandoz Inc. submitted a declaration by Rüdiger Jankowsky which stated that he worked for "Sandoz." According to his LinkedIn profile, at the time Jankowsky worked for "Sandoz Biopharmaceuticals/Novartis" in Holzkirchen, Germany—the location of Sandoz International GmbH's principal place of business.

22. As another example, during the same prior litigation brought by Sandoz Inc. concerning the '182 and '522 patents, Sandoz Inc. submitted a declaration by Karsten Roth

which stated that he was employed by "Sandoz Inc." However, according to his LinkedIn profile, at the time of his declaration he was employed by "Sandoz" in the "Munich Area, Germany." Upon information and belief, Roth attended meetings with the FDA to discuss Defendants' aBLA and encouraged the FDA to approve Defendants' aBLA.

C. **Sandoz International GmbH**

23. Upon information and belief, Sandoz International GmbH collaborates with Sandoz Inc. to develop, manufacture, seek approval for, and sell FDA-approved biopharmaceutical drugs, which are being marketed, distributed, and sold in New Jersey and in the United States.

24. Upon information and belief, Sandoz International GmbH exercises considerable control over Sandoz Inc. with respect to biosimilar products, and approves significant decisions of Sandoz Inc. such as allowing Sandoz Inc. to act as the agent for Sandoz International GmbH in connection with preparing and filing Defendants' aBLA and to act as Sandoz International GmbH's agent in the United States. For example, the Sandoz Management Team includes "Richard Francis, Global Head of Sandoz," and "Peter Goldschmidt, President of Sandoz US and Head of North America." Upon information and belief, Mr. Francis is the head of Sandoz International GmbH, Mr. Goldschmidt is the President of Sandoz Inc. as well as the Head of North American Operations at Sandoz International GmbH, and Mr. Goldschmidt directly or indirectly reports to Mr. Francis.

25. Upon information and belief, employees or officers of Sandoz International GmbH, such as Mark McCamish and Ingrid Schwarzenberger, have attended meetings with the FDA to discuss Defendants' aBLA and have encouraged the FDA to approve Defendants' aBLA.

26. In addition, Sandoz International GmbH and Sandoz Inc. hold themselves out as a unitary entity and have represented to the public that the activities of Sandoz International GmbH

and Sandoz Inc. are directed, controlled, and carried out as a single entity. For example, Sandoz maintains an Internet website at the URL www.sandoz.com attached hereto as Exhibit A, which states that it is "the website of Sandoz International" and on which Sandoz states that all of the worldwide generic pharmaceutical businesses owned by Novartis operate "under one single global brand as known today: Sandoz."

27. Upon information and belief, Sandoz International GmbH is actively involved in planning Sandoz Inc.'s new products and filing Defendants' aBLA for the biosimilar product in dispute. For example, Sandoz Inc.'s President, Mr. Goldschmidt, is also the Head of North American Operations at Sandoz International GmbH.

28. Upon information and belief, Sandoz International GmbH acted in concert with Sandoz Inc. to develop a biosimilar version of ENBREL®. Upon information and belief, Sandoz International GmbH acted in concert with, directed, or authorized Sandoz Inc. to file an aBLA seeking approval from the FDA to market and sell Defendants' biosimilar product in the State of New Jersey and throughout the United States, which directly gives rise to Plaintiffs' claims of patent infringement. For example, Novartis AG, the ultimate corporate parent of both Sandoz International GmbH and Sandoz Inc., issued a press release on October 2, 2015, from Holzkirchen, Germany announcing that the FDA had accepted an application by "Sandoz" for biosimilar etanercept. *See* Press Release, Novartis, "FDA accepts Sandoz regulatory submission for a proposed biosimilar etanercept" (Oct. 2, 2015), https://www.novartis.com/news/media-releases/fda-accepts-sandoz-regulatory-submission-proposed-biosimilar-etanercept, attached hereto as Exhibit B. Upon information and belief, the press release announcing the FDA's acceptance of Defendants' aBLA, which is the subject of Plaintiffs' claims, was issued on behalf of Sandoz International GmbH.

29. Upon information and belief, the acts of Sandoz Inc. complained of herein were done, in part, for the benefit of Sandoz International GmbH. Upon information and belief, Sandoz International GmbH directly or indirectly manufactures, imports into the United States, or sells Defendants' biosimilar product that is the subject of the infringement claims in this action in New Jersey and throughout the United States.

30. Additionally, and in the alternative, Immunex/AML and Roche allege that to the extent Sandoz International GmbH is not subject to the jurisdiction of the courts of general jurisdiction of the State of New Jersey, Sandoz International GmbH likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

D. **Sandoz GmbH**

31. Upon information and belief, Sandoz GmbH collaborates with Sandoz Inc. to develop, manufacture, seek approval for, and sell FDA-approved biopharmaceutical drugs, which are being marketed, distributed, and sold in New Jersey and in the United States.

32. Sandoz GmbH and Sandoz Inc. hold themselves out as a unitary entity and have represented to the public that the activities of Sandoz GmbH and Sandoz Inc. are directed, controlled, and carried out as a single entity. For example, Sandoz maintains an Internet website at the URL www.sandoz.com, attached hereto Exhibit A, which states that it is "the website of Sandoz International" and on which Sandoz states that all of the worldwide generic pharmaceutical businesses owned by Novartis operate "under one single global brand as known today: Sandoz."

33. Upon information and belief, Sandoz GmbH is actively involved with planning Sandoz Inc.'s new biosimilar etanercept products and filing Defendants' aBLA for the biosimilar product in dispute. Title 42 U.S.C. § 262(k)(2)(A)(V) provides that a biosimilar application submitted to the FDA under the § 262(k) pathway "shall include" information demonstrating "the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent." Upon information and belief, Defendants' biosimilar product that is the subject of Defendants' aBLA is manufactured at Sandoz GmbH facilities. Therefore, upon information and belief, Sandoz GmbH actively participated in the preparation of Defendants' aBLA, for example by providing information regarding the facilities in which Defendants' biosimilar product is manufactured, processed, packed, or held.

34. Upon information and belief, Sandoz GmbH acted in concert with Sandoz Inc. to develop a biosimilar version of ENBREL®. Upon information and belief, Sandoz GmbH acted in concert with, directed, or authorized Sandoz Inc. to file an aBLA seeking approval from the FDA to market and sell Defendants' biosimilar product in the State of New Jersey and throughout the United States, which directly gives rise to Plaintiffs' claims of patent infringement.

35. Upon information and belief, employees or officers of Sandoz GmbH, such as Fritz Reiter and Thomas Stangler, have attended meetings with the FDA to discuss Defendants' aBLA and have encouraged the FDA to approve Defendants' aBLA.

36. Upon information and belief, employees or officers of Sandoz GmbH, such as Albrecht Ralf, have signed certifications which were executed to be included as part of Defendants' aBLA.

37. Upon information and belief, the acts of Sandoz Inc. complained of herein were done, in part, for the benefit of Sandoz GmbH. Upon information and belief, Sandoz GmbH directly or indirectly manufactures, imports into the United States, or sells Defendants' biosimilar product that is the subject of the infringement claims in this action in New Jersey and throughout the United States.

38. Additionally, and in the alternative, Plaintiffs allege that to the extent Sandoz GmbH is not subject to the jurisdiction of the courts of general jurisdiction of the State of New Jersey, Sandoz GmbH likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

E. **Venue**

39. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b). On information and belief, Defendants manufacture, seek regulatory approval to market, distribute, and sell pharmaceutical products, and market, distribute, and sell pharmaceutical products for use throughout the United States, including in this District.

IV. BACKGROUND

A. **TNF and TNF Receptors**

40. Tumor necrosis factor ("TNF") is a cell signaling protein that is involved in various biological effects that include the regulation of immune response, inflammation, and other processes. It was first identified as an agent that has cytotoxic effects on tumor cells, and hence was named "tumor necrosis factor." Overproduction of TNF in the body is also implicated in various autoimmune diseases and other inflammatory disorders.

41. The biological effects of TNF can be mediated via specific receptors that are found on the membranes of certain cells. TNF receptors on the surface of the cells can specifically bind to TNF. This binding can trigger reactions inside the cell, which can give rise to a number of different responses, including inflammation, cell growth, and cell death.

42. Two cell membrane-bound receptors specific to TNF are sometimes referred to as the "p55 TNF receptor" and the "p75 TNF receptor."

B. **Immunex's Investment in ENBREL® (etanercept)**

43. The active ingredient in ENBREL® is etanercept, a genetically engineered, non-naturally occurring fusion protein that binds to and inhibits TNF from binding to a TNF receptor.

44. The etanercept fusion protein was genetically engineered to fuse the extracellular region of the human p75 version of the TNF receptor with a portion of a human immunoglobulin heavy chain (*i.e.*, a portion of a human antibody).

45. By binding to and inhibiting TNF from interacting with TNF receptors, ENBREL® can reduce certain inflammatory responses implicated in certain disorders such as rheumatoid arthritis, psoriasis, and psoriatic arthritis, and others.

46. The FDA has approved ENBREL® for the following indications: rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. The availability of ENBREL® represented a major advance in the treatment of these disorders.

47. Immunex conducted Phase I testing to determine whether ENBREL® was safe to administer to patients with rheumatoid arthritis; results published in 1993 indicated that it was. Immunex then conducted Phase II testing to begin determining whether ENBREL® improved symptoms of rheumatoid arthritis; results indicating that it did improve symptoms were published in 1996. Immunex conducted Phase III testing and invested a substantial amount of

time and resources testing ENBREL® to demonstrate that it was safe and effective for certain disorders.

48. Based on the results of clinical testing in rheumatoid arthritis, Immunex filed Biologic License Application ("BLA") No. 103795. As a result, in November 1998, the FDA first approved ENBREL®, pursuant to BLA No. 103795, for the treatment of moderate to severe rheumatoid arthritis. Immunex holds the rights to BLA No. 103795.

49. Other clinical testing revealed that ENBREL® was safe and effective for certain additional diseases. Based on Immunex's further clinical testing, Immunex filed supplements to BLA No. 103795, requesting that ENBREL® be approved for certain additional indications. As a result, the FDA approved ENBREL® for the treatment of polyarticular juvenile idiopathic arthritis in 1999, psoriatic arthritis in 2002, ankylosing spondylitis in 2003, and plaque psoriasis in 2004. These approvals are the direct result of very significant investments by Immunex in the development and clinical trials of ENBREL®.

C. **Defendants' Abbreviated BLA**

50. Defendants are piggybacking on the fruits of Immunex/AML and Roche's trailblazing efforts. Defendants have publicly announced that they filed their aBLA under the (k) pathway to obtain approval to commercially manufacture, use, offer to sell, and sell, and import into the United States their etanercept product that they assert is a biosimilar version of Immunex's ENBREL®.

51. Defendants have also chosen to benefit from the clinical data generated by Immunex/AML's investments demonstrating the therapeutic indications for which ENBREL® is effective. Defendants issued a press release stating that "Sandoz is seeking approval for all indications included in the label of the reference product which is used to treat a range of autoimmune diseases including rheumatoid arthritis and psoriasis affecting approx. 1.3 million

and 7.5 million people (respectively) in the US" (footnotes omitted). *See* Press Release, Novartis, "FDA accepts Sandoz regulatory submission for a proposed biosimilar etanercept" (Oct. 2, 2015), https://www.novartis.com/news/media-releases/fda-accepts-sandoz-regulatory-submission-proposed-biosimilar-etanercept, attached hereto as Exhibit B.

52. On information and belief, Defendants conducted clinical trials only for the use of their biosimilar drug product on psoriasis patients, despite the breadth of their request to the FDA for approval for other indications, such as rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, and ankylosing spondylitis.

53. On information and belief, Defendants did not conduct any clinical trials on indications for which ENBREL® had not already been demonstrated to be safe and effective.

54. On information and belief, the amino acid sequence of Defendants' etanercept fusion protein is the same amino acid sequence of the etanercept fusion protein in ENBREL®.

55. On information and belief, Defendants have represented to the FDA that their etanercept product is biosimilar to Immunex's ENBREL®. As such, on information and belief, Defendants' etanercept product utilizes the same mechanism of action as ENBREL® for the conditions of use prescribed, recommended, or suggested in ENBREL®'s approved label. In addition, the route of administration, the dosage form, and the strength of Defendants' etanercept product are the same as those of Immunex's ENBREL®. *See* 42 U.S.C. § 262(k)(2)(A)(i).

D. **Defendants' Refusal to Comply with the BPCIA**

56. Defendants have—for the second time—tried to reap the commercial benefits provided to biosimilar manufacturers under the BPCIA while seeking to avoid the obligations in that same Act that Congress established to protect innovators such as Immunex/AML and Roche.

57. On October 19, 2015, which was, on information and belief, 20 days after the FDA notified Sandoz Inc. that its aBLA had been accepted for review, Sandoz Inc. provided

Immunex with remote access to a Sandoz-hosted database of TIFF images, modified to include added confidentiality designations, that Sandoz Inc. represented to constitute its aBLA and information relating to the manufacturing process for Defendants' biosimilar product. The manner in which this database access was provided would not have allowed Immunex local access and evaluation except after manual download of the thousands of documents included therein, along with a folder-by-folder manual reconstruction of the database's directory structure. Sandoz Inc. did not provide a local copy of the database—including the necessary database load files and associated data—and an unaltered copy of the aBLA in the same electronic format as submitted to FDA until October 28, 2015.

58. On November 9, 2015, determining that Sandoz had failed to provide complete information describing the processes used to manufacture the biological product that is the subject of Defendants' aBLA, Immunex requested that Sandoz Inc. provide further information.

59. On November 16, 2015, Sandoz Inc. provided additional documents which it represented to relate to the manufacturing process for Defendants' biosimilar product.

60. Notwithstanding issues with the timeliness and completeness of the information Sandoz Inc. had provided, in respect of 42 U.S.C. § 262(*l*)(3)(A), Immunex nevertheless provided to Sandoz Inc. on December 18, 2015 a list of patents for which a claim of infringement could be reasonably asserted based on Defendants' etanercept product.

61. On January 27, 2016, Sandoz Inc. responded to Immunex's list of patents by stating that it no longer wished to follow the strictures of the BPCIA. Specifically, Sandoz Inc. sent Immunex a 86-page letter stating its patent contentions but "agreeing" with Immunex's 42 U.S.C. § 262(*l*)(3)(A) list. Sandoz Inc. also stated it was "waiving" its right to receive a statement by Immunex pursuant to 42 U.S.C. § 262(*l*)(3)(C), and declared that negotiations

pursuant to 42 U.S.C. § 262(*l*)(4) and (5) were unnecessary. Sandoz Inc. then insisted that Immunex file an action for patent infringement pursuant to 42 U.S.C. § 262(*l*)(6) within 30 days, *i.e.*, by February 26, 2016. Also on January 27, 2016, Sandoz Inc. provided additional documents which it represented provided even more information relating to the manufacturing process for Defendants' biosimilar product.

62. On February 10, 2016, Immunex explained to Sandoz Inc. that its refusal to participate in negotiations pursuant to 42 U.S.C. § 262(*l*)(4) and (5) was contrary to the text of the statute. Immunex also requested that Sandoz Inc. withdraw its refusal to participate in the statutory process set forth in 42 U.S.C. § 262(*l*)(4) and (5), and explained that Sandoz Inc.'s failure to do so implicated 42 U.S.C. § 262(*l*)(9), which authorizes the reference product sponsor, but not the subsection (k) applicant, to file a declaratory judgment action on patents that are or would be infringed by the biosimilar applicant (Sandoz Inc.).

63. On February 17, 2016, Sandoz Inc. confirmed its refusal to participate in negotiations pursuant to 42 U.S.C. § 262(*l*)(4) and (5), and stated that it wished for patent litigation to begin as soon as possible. No list of patents for Defendants' etanercept biosimilar product was generated as described in 42 U.S.C. § 262(*l*)(4) or as described in 42 U.S.C. § 262(*l*)(5).

64. Defendants have failed to participate, and thus, have not complied with the process defined in the statute that must precede an "immediate patent infringement action" under 42 U.S.C. § 262(*l*)(6). By refusing to participate in a timely and complete manner under the BPCIA, including by seeking to extinguish Immunex's ability to consider and respond to Sandoz Inc.'s contentions regarding the patents that Immunex had properly identified and entirely evading the negotiations specified in 42 U.S.C. § 262(*l*)(4) and (5), Sandoz Inc. has repudiated

its obligations under the BPCIA. Thus, in addition to bringing an action under 35 U.S.C. § 271(e)(2)(C), Immunex—but not Defendants—pursuant to 42 U.S.C. § 262(*l*)(9) may bring a declaratory action on patents related to Defendants' biosimilar product.

V. THE PATENTS-IN-SUIT

A. The '182 and '522 Patents

65. In the late 1980s, Roche and Immunex scientists were early pioneers in isolating, characterizing, cloning, and sequencing p55 and p75 versions of the human TNF receptors, respectively.

66. Roche scientists were the first to clone and sequence the human p55 TNF receptor gene and determine the amino acid sequence of the receptor. They published the sequence of this receptor on April 20, 1990. *See* Loetscher et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor," *Cell* 61:351-359 (April 20, 1990).

67. Immunex scientists were the first to clone and sequence the p75 TNF receptor gene and determine the amino acid sequence of the receptor. They published the sequence of the human p75 TNF receptor later the same year. *See* Smith et al., "A Receptor for Tumor Necrosis Factor Defines an Unusual Family of Cellular and Viral Proteins," *Science* 248:1019-1023 (1989).

68. On August 31, 1990, Roche scientists filed European Patent Application No. 90116707.2, which disclosed and taught the novel concept of fusing of the extracellular fragment of the TNF receptors with a portion of the human immunoglobulin heavy chain (*i.e.*, all of the domains of the constant region of a human immunoglobulin IgG heavy chain other than the first domain of said constant region). These Roche scientists also filed a United States patent application on September 10, 1990, which claimed priority to said European patent application.

69. The ’182 and ’522 patents issued from applications that claim priority to the European patent application filed on August 31, 1990.

70. The ’182 patent is directed to a fusion protein incorporating a portion of the p75 TNF receptor and covers etanercept. The ’522 patent is directed to nucleic acids, host cells, and methods of using such nucleic acids and host cells to make the p75 TNF receptor fusion protein.

B. **The ’225, ’605, and ’631 Patents**

71. In developing etanercept as a therapeutic, Immunex also developed and obtained patents directed toward using etanercept to treat psoriasis and/or psoriatic arthritis. The ’225 patent, the ’605 patent, and the ’631 patent (“the Psoriasis Patents”), owned by Immunex, disclose and claim methods of using etanercept to treat psoriasis and/or psoriatic arthritis.

72. Psoriasis is a chronic inflammatory disease of the skin and joints. It results in scaly growths on the skin of affected patients, which can be disfiguring and extremely uncomfortable.

73. Psoriatic arthritis is an inflammatory arthritis characterized by joint pain, stiffness, and swelling. It can cause to joint damage which limits daily activities.

74. In the late 1990s, there were no biologic therapies approved to treat psoriasis or psoriatic arthritis.

75. Dermatologists had used various other therapeutic approaches to treating psoriasis, such as methotrexate, psoralen and ultraviolet A radiation, and cyclosporine. However, each of these therapies was found to have serious side effects, such as liver damage, skin damage, and kidney damage, respectively, after they had been used for many years.

76. The Psoriasis Patents claim priority to a provisional application filed on August 11, 1999. The Psoriasis Patents also claim priority to non-provisional applications filed August 13, 1999, and June 23, 2000.

77. As a general matter, the Psoriasis Patents contain claims to using etanercept to treat psoriasis and/or psoriatic arthritis, and further specify certain dosage regimes to follow.

78. The manner in which ENBREL® is commonly used to treat psoriasis (or psoriasis and psoriatic arthritis) today falls within the scope of the claims of the Psoriasis Patents.

COUNT 1: INFRINGEMENT OF THE '182 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)

79. Immunex/AML and Roche incorporate by reference paragraphs 1-70 as if fully set forth herein.

80. The '182 patent, titled "Human TNF Receptor Fusion Protein," was duly and legally issued on November 22, 2011 by the United States Patent and Trademark Office ("USPTO"). A true and correct copy of the '182 patent is attached to this Complaint as Exhibit C.

81. The claims of the '182 patent cover etanercept and pharmaceutical compositions that are made from etanercept.

82. Defendants have infringed the '182 patent by submitting an aBLA referencing Immunex's ENBREL® product and seeking FDA approval under 42 U.S.C. § 262(k) to manufacture, import, offer to sell, or sell within the United States the product that is the subject of that application.

83. On December 18, 2015, Immunex, as the reference product sponsor for ENBREL®, identified the '182 patent to Sandoz pursuant to 42 U.S.C. § 262(*l*)(3)(A).

84. Defendants have known of the '182 patent since at least June 2013. Despite such knowledge, Defendants nonetheless filed their aBLA with the FDA in July 2015 seeking approval of Defendants' etanercept biosimilar product, with the intent to import, offer to sell, and sell their biosimilar product within the United States before the expiration of the '182 patent and in violation of Immunex/AML and Roche's patent rights.

85. Immunex/AML and/or Roche will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '182 patent. Immunex/AML and Roche do not have an adequate remedy at law and are entitled to injunctive relief preventing Defendants from any further infringement.

86. Defendants' commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, upon FDA approval of Defendants' etanercept biosimilar product and before the expiration of the '182 patent, will cause injury to Immunex/AML and Roche, entitling them to damages or other monetary relief.

COUNT 2: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '182 PATENT UNDER 35 U.S.C. § 271(a)

87. Immunex/AML and Roche incorporate by reference paragraphs 1-70 as if fully set forth herein.

88. Defendants have sought FDA approval under 42 U.S.C. § 262(k) to manufacture, use, import, offer to sell, or sell within the United States Defendants' etanercept biosimilar product, a biosimilar version of ENBREL® (etanercept).

89. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt. On information and belief, Defendants believe that the FDA may act upon Defendants' aBLA as soon as May 2016, and that Defendants will be able to pay the user fee prescribed under the Prescription Drug User Fee Act by that time.

90. On information and belief, Defendants intend to, and will immediately and imminently upon FDA licensure of Defendants' aBLA, notwithstanding the clear requirements of § 262(*l*)(8), import and offer to sell or sell within the United States Defendants' etanercept biosimilar product, which will infringe one or more claims of the '182 patent under 35 U.S.C. § 271(a).

91. An actual controversy has arisen and now exists between the parties concerning whether Defendants' etanercept biosimilar product has or will infringe one or more claims of the '182 patent.

92. Defendants also have failed to complete the actions required of them under 42 U.S.C. § 262(*l*)(4) and (5) by failing to engage in negotiation and exchange of patent lists under 42 U.S.C. § 262(*l*)(4) and 262(*l*)(5). No list of patents for Defendants' etanercept biosimilar product was generated as described in 42 U.S.C. § 262(l)(4) or as described in 42 U.S.C. § 262(*l*)(5).

93. Immunex/AML and Roche are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '182 patent by making, using, offering to sell, or selling within the United States, or importing into the United States Defendants' etanercept biosimilar product before the expiration of the '182 patent.

94. Immunex/AML and Roche do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States Defendants' etanercept biosimilar product before the expiration of the '182 patent.

95. Defendants' manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' etanercept biosimilar product before the expiration of the '182 patent will cause injury to Immunex/AML and Roche, entitling them to damages under 35 U.S.C. § 284.

COUNT 3: INFRINGEMENT OF THE '522 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)

96. Immunex/AML and Roche incorporate by reference paragraphs 1-70 as if fully set forth herein.

97. The '522 patent, titled "Human TNF Receptor," was duly and legally issued on April 24, 2012 by the USPTO. A true and correct copy of the '522 patent is attached to this Complaint as Exhibit D.

98. The claims of the '522 patent cover, among other things, methods of making etanercept and certain materials used in such methods.

99. Defendants have infringed the '522 patent by submitting an aBLA referencing Immunex's ENBREL® product and seeking FDA approval under 42 U.S.C. § 262(k) to manufacture, import, offer to sell, or sell within the United States the product that is the subject of that application.

100. On December 18, 2015, Immunex, as the reference product sponsor for ENBREL®, identified the '522 patent to Sandoz Inc. pursuant to 42 U.S.C. § 262(*l*)(3)(A).

101. Defendants have known of the '522 patent since at least June 2013. Despite such knowledge, Defendants nonetheless filed their aBLA with the FDA in July 2015 seeking approval of Defendants' etanercept biosimilar product that was manufactured by the methods of the '522 patent, with the intent to import, offer to sell, and sell their biosimilar product within the United States before the expiration of the '522 patent and in violation of Immunex/AML and Roche's patent rights.

102. Immunex/AML and Roche will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '522 patent. Immunex/AML and Roche do not have an adequate remedy at law and are entitled to injunctive relief preventing Defendants from any further infringement.

103. Defendants' commercial manufacture of Defendants' etanercept product, and their subsequent importation for sale within the United States, upon FDA approval of

Defendants' etanercept biosimilar product and before the expiration of the '522 patent will cause injury to Immunex/AML and Roche, entitling them to damages or other monetary relief.

COUNT 4: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '522 PATENT UNDER 35 U.S.C. § 271(g)

104. Immunex/AML and Roche incorporate by reference paragraphs 1-70 as if fully set forth herein.

105. On information and belief, Defendants intend to, and will immediately and imminently upon FDA licensure of Defendants' aBLA, manufacture Defendants' etanercept product according to the process described in their aBLA and import and offer to sell or sell within the United States Defendants' etanercept biosimilar product made by such process, which will infringe the method claims of the '522 patent under 35 U.S.C. § 271(g).

106. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt. On information and belief, Defendants believe that the FDA may act upon Defendants' aBLA as soon as May 2016, and that Defendants will be able to pay the user fee prescribed under the Prescription Drug User Fee Act by that time.

107. On information and belief, Defendants intend to, and will immediately and imminently upon FDA licensure of Defendants' aBLA, notwithstanding the clear requirements of 42 U.S.C. § 262(*l*)(8), import and offer to sell or sell within the United States Defendants' etanercept biosimilar product, which will infringe one or more claims of the '522 patent under 35 U.S.C. § 271(g).

108. The etanercept made by Defendants' process that infringes the '522 patent is the essential active ingredient of Defendants' biological drug product. On information and belief, there is no subsequent process that materially changes that active ingredient, including during any fill and finish of the biological product.

109. An actual controversy has arisen and now exists between the parties concerning whether Defendants' etanercept biosimilar product has infringed or will infringe one or more claims of the '522 patent.

110. Defendants also have failed to complete the actions required of them under 42 U.S.C. § 262(*l*)(4) and (5) by failing to engage in negotiation and exchange of patent lists under 42 U.S.C. § 262(*l*)(4) and 262(*l*)(5). No list of patents for Defendants' etanercept biosimilar product was generated as described in 42 U.S.C. § 262(*l*)(4) or as described in 42 U.S.C. § 262(*l*)(5).

111. Immunex/AML and Roche are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '522 patent by making Defendants' etanercept biosimilar product and importing it into the United States for sale in the United States, before the expiration of the '522 patent.

112. Immunex/AML and Roche do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Defendants from making, importing into, and selling within the United States Defendants' etanercept biosimilar product before the expiration of the '522 patent.

113. Defendants' making, importing, and selling within the United States of Defendants' etanercept biosimilar product before the expiration of the '522 patent will cause Immunex/AML and Roche injury, entitling them to damages under 35 U.S.C. § 284.

COUNT 5: INFRINGEMENT OF THE '225 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)

114. Immunex/AML incorporate by reference paragraphs 1-113 as if fully set forth herein.

115. The ’225 patent, titled “Soluble Tumor Necrosis Factor Receptor Treatment of Medical Disorders” was duly and legally issued on March 29, 2011 by the USPTO. A true and correct copy of the ’225 patent is attached to this Complaint as Exhibit E.

116. The ’225 patent is generally directed to methods of treating psoriasis and/or psoriatic arthritis by administering etanercept.

117. Defendants have infringed the ’225 patent by submitting an aBLA referencing Immunex’s ENBREL® product and seeking FDA approval under 42 U.S.C. § 262(k) to manufacture, import, offer to sell, or sell within the United States the product that is the subject of that application.

118. With the intent to infringe the ’225 patent, Defendants submitted their aBLA seeking FDA approval under 42 U.S.C. § 262(k) to market, offer to sell, or sell within the United States Defendants’ etanercept biosimilar product for the treatment of psoriasis or psoriatic arthritis. On information and belief, Defendants conducted clinical trials of their etanercept biosimilar product for the psoriasis indication only. On information and belief, Defendants copied ENBREL®’s labeling that instructs physicians and patients to administer etanercept subcutaneously for treatment of psoriasis or psoriatic arthritis in specific dosages, which is covered by the ’225 patent.

119. On information and belief, Defendants knew of the ’225 patent before July 2015. Despite such knowledge, Defendants nonetheless filed their aBLA with the FDA in July 2015 seeking approval of Defendants’ etanercept biosimilar product, with the intent to import, market, offer to sell, and sell their biosimilar product for psoriasis and/or psoriatic arthritis within the United States before the expiration of the ’225 patent and in violation of Immunex/AML’s patent rights.

120. On December 18, 2015, Immunex, as the reference product sponsor for ENBREL®, identified the '225 patent to Sandoz Inc. pursuant to 42 U.S.C. § 262(*l*)(3)(A).

121. Immunex/AML will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '225 patent. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief preventing Defendants from any further infringement.

122. Defendants' commercial marketing, offer for sale, or sale within the United States, upon FDA approval of Defendants' etanercept biosimilar product for use with psoriasis and/or psoriatic arthritis before the expiration of the '225 patent, will cause injury to Immunex/AML, entitling Immunex/AML to damages or other monetary relief.

COUNT 6: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '225 PATENT UNDER 35 U.S.C. § 271(b)

123. Immunex/AML incorporate by reference paragraphs 1-122 as if fully set forth herein.

124. Defendants have sought FDA approval under 42 U.S.C. § 262(k) to import, market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product, a biosimilar version of ENBREL® (etanercept), for treating psoriasis and psoriatic arthritis.

125. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt. On information and belief, Defendants believe that the FDA may act upon Defendants' aBLA as soon as May 2016, and that Defendants will be able to pay the user fee prescribed under the Prescription Drug User Fee Act by that time.

126. On information and belief, Defendants intend to, and will immediately and imminently upon FDA licensure of Defendants' aBLA, notwithstanding the clear requirements of § 262(*l*)(8), import, market, offer to sell, or sell within the United States Defendants'

etanercept biosimilar product for treating psoriasis and/or psoriatic arthritis, which use by physicians and patients will infringe one or more claims of the '225 patent under 35 U.S.C. § 271(b).

127. An actual controversy has arisen and now exists between the parties concerning whether Defendants will induce infringement by physicians and patients of the '225 patent by their marketing and sales of their etanercept biosimilar product for psoriasis and/or psoriatic arthritis.

128. Defendants also have failed to complete the actions required of them under 42 U.S.C. § 262(*l*)(4) and (5) by failing to engage in negotiation and exchange of patent lists under 42 U.S.C. § 262(*l*)(4) and 262(*l*)(5). No list of patents for Defendants' etanercept biosimilar product was generated as described in 42 U.S.C. § 262(*l*)(4) or as described in 42 U.S.C. § 262(*l*)(5).

129. Immunex/AML are entitled to a declaratory judgment that Defendants have infringed, will infringe, or will induce infringement of one or more claims of the '225 patent by marketing, offering to sell, or selling within the United States Defendants' etanercept biosimilar product for treatment of psoriasis and/or psoriatic arthritis before the expiration of the '225 patent.

130. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Defendants from making, importing into, and selling within the United States Defendants' etanercept biosimilar product before the expiration of the '225 patent.

131. Defendants' marketing, offer for sale, or sale within the United States of Defendants' etanercept biosimilar product for treating psoriasis and/or psoriatic arthritis before

the expiration of the '225 patent will cause Immunex/AML injury, entitling them to damages under 35 U.S.C. § 284.

COUNT 7: INFRINGEMENT OF THE '605 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)

132. Immunex/AML incorporate by reference paragraphs 1-131 as if fully set forth herein.

133. The '605 patent, titled "Soluble Tumor Necrosis Factor Receptor Treatment of Medical Disorders" was duly and legally issued on February 21, 2012 by the USPTO. A true and correct copy of the '605 patent is attached to this Complaint as Exhibit F.

134. The '605 patent is generally directed to methods of treating psoriasis by administering etanercept.

135. Defendants have infringed the '605 patent by submitting an aBLA referencing Immunex's ENBREL® product and seeking FDA approval under 42 U.S.C. § 262(k) to manufacture, import, offer to sell, or sell within the United States the product that is the subject of that application.

136. With the intent to infringe the '605 patent, Defendants submitted their aBLA seeking FDA approval under 42 U.S.C. § 262(k) to market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product for the treatment of psoriasis. On information and belief, Defendants conducted clinical trials of their etanercept biosimilar product for the psoriasis indication only. On information and belief, Defendants copied ENBREL®'s labeling that instructs physicians and patients to administer etanercept for treating psoriasis in specific dosages, which is covered by the '605 patent.

137. On information and belief, Defendants knew of the '605 patent before July 2015. Despite such knowledge, Defendants nonetheless filed their aBLA with the FDA in July 2015 seeking approval of Defendants' etanercept biosimilar product, with the intent to import, market,

offer to sell, and sell their biosimilar product for treating psoriasis within the United States before the expiration of the '605 patent and in violation of Immunex/AML's patent rights.

138. On December 18, 2015, Immunex, as the reference product sponsor for ENBREL®, identified the '605 patent to Sandoz Inc. pursuant to 42 U.S.C. § 262(*l*)(3)(A).

139. Immunex/AML will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '605 patent. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief preventing Defendants from any further infringement.

140. Defendants' commercial marketing, offer for sale, or sale within the United States, upon FDA approval of Defendants' etanercept biosimilar product for treating psoriasis and before the expiration of the '605 patent, will cause injury to Immunex/AML, entitling Immunex/AML to damages or other monetary relief.

COUNT 8: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '605 PATENT UNDER 35 U.S.C. § 271(b)

141. Immunex/AML incorporate by reference paragraphs 1-140 as if fully set forth herein.

142. Defendants have sought FDA approval under 42 U.S.C. § 262(k) to import, market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product, a biosimilar version of ENBREL® (etanercept), for treating psoriasis.

143. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt. On information and belief, Defendants believe that the FDA may act upon Defendants' aBLA as soon as May 2016, and that Defendants will be able to pay the user fee prescribed under the Prescription Drug User Fee Act by that time.

144. On information and belief, Defendants intend to, and will immediately and imminently upon FDA licensure of Defendants' aBLA, notwithstanding the clear requirements of 42 U.S.C. § 262(*l*)(8), import, market, offer to sell, or sell within the United States the Sandoz etanercept biosimilar product for treating psoriasis, which use by physicians and patients will infringe one or more claims of the '605 patent under 35 U.S.C. § 271(b).

145. An actual controversy has arisen and now exists between the parties concerning whether Sandoz will induce infringement by physicians and patients of the '605 patent by their marketing and sales of Defendants' etanercept biosimilar product for psoriasis.

146. Defendants also have failed to complete the actions required of them under 42 U.S.C. § 262(*l*)(4) and (5) by failing to engage in negotiation and exchange of patent lists under 42 U.S.C. § 262(*l*)(4) and 262(*l*)(5). No list of patents for Defendants' etanercept biosimilar product was generated as described in 42 U.S.C. § 262(*l*)(4) or as described in 42 U.S.C. § 262(*l*)(5).

147. Immunex/AML are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '605 patent by marketing, offering to sell, or selling within the United States Defendants' etanercept biosimilar product for treatment of psoriasis before the expiration of the '605 patent.

148. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Defendants from making, importing into, and selling within the United States Defendants' etanercept biosimilar product before the expiration of the '605 patent.

149. Defendants' marketing, offer for sale, or sale within the United States of the Sandoz etanercept biosimilar product for treating psoriasis before the expiration of the '605 patent will cause Immunex/AML injury, entitling them to damages under 35 U.S.C. § 284.

COUNT 9: INFRINGEMENT OF THE '631 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)

150. Immunex/AML incorporate by reference paragraphs 1-149 as if fully set forth herein.

151. The '631 patent, titled "Soluble Tumor Necrosis Factor Receptor Treatment of Medical Disorders" was duly and legally issued on May 13, 2014 by the USPTO. A true and correct copy of the '631 patent is attached to this Complaint as Exhibit G.

152. The '631 patent is generally directed to methods of treating psoriasis and/or psoriatic arthritis by administering etanercept.

153. Defendants have infringed the '631 patent by submitting an aBLA referencing Immunex's ENBREL® product and seeking FDA approval under 42 U.S.C. § 262(k) to manufacture, import, offer to sell, or sell within the United States the product that is the subject of that application.

154. With the intent to infringe the '631 patent, Defendants submitted their aBLA seeking FDA approval under 42 U.S.C. § 262(k) to market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product for the treatment of psoriasis and psoriatic arthritis. On information and belief, Defendants conducted clinical trials of their etanercept biosimilar product for the psoriasis indication only. On information and belief, Defendants copied ENBREL®'s labeling that instructs physicians and patients to administer etanercept subcutaneously for treatment of psoriasis or psoriatic arthritis in specific dosages, which is covered by the '631 patent.

155. On information and belief, Defendants knew of the '631 patent before July 2015. Despite such knowledge, Defendants nonetheless filed their aBLA with the FDA in July 2015 seeking approval of Defendants' etanercept biosimilar product, with the intent to import, market, offer to sell, and sell their biosimilar product for psoriasis and/or psoriatic arthritis within the

United States before the expiration of the '631 patent and in violation of Immunex/AML's patent rights.

156. On December 18, 2015, Immunex, as the reference product sponsor for ENBREL®, identified the '631 patent to Sandoz Inc. pursuant to 42 U.S.C. § 262(*l*)(3)(A).

157. Immunex/AML will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '631 patent. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief preventing Defendants from any further infringement.

158. Defendants' commercial marketing, offer for sale, or sale within the United States, upon FDA approval of Defendants' etanercept biosimilar product for use in psoriasis or psoriatic arthritis and before the expiration of the '631 patent, will cause injury to Immunex/AML, entitling Immunex/AML to damages or other monetary relief.

COUNT 10: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '631 PATENT UNDER 35 U.S.C. § 271(b)

159. Immunex/AML incorporate by reference paragraphs 1-158 as if fully set forth herein.

160. Defendants have sought FDA approval under 42 U.S.C. § 262(k) to import, market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product, a biosimilar version of ENBREL® (etanercept), for treating psoriasis and/or psoriatic arthritis.

161. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt. On information and belief, Defendants believe that the FDA may act upon Defendants' aBLA as soon as May 2016, and Defendants will be able to pay the user fee prescribed under the Prescription Drug User Fee Act by that time.

162. On information and belief, Defendants intend to, and will immediately and imminently upon FDA licensure of Defendants' aBLA, notwithstanding the clear requirements of 42 U.S.C. § 262(*l*)(8), import, market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product for treating psoriasis and/or psoriatic arthritis, which use by physicians and patients will infringe one or more claims of the '631 patent under 35 U.S.C. § 271(b).

163. An actual controversy has arisen and now exists between the parties concerning whether Defendants will induce infringement by physicians and patients of the '631 patent by their marketing and sales of Defendants' etanercept biosimilar product for psoriasis and/or psoriatic arthritis.

164. Defendants also have failed to complete the actions required of Defendants under 42 U.S.C. § 262(*l*)(4) and (5) by failing to engage in negotiation and exchange of patent lists under 42 U.S.C. § 262(*l*)(4) and 262(*l*)(5). No list of patents for Defendants' etanercept biosimilar product was generated as described in 42 U.S.C. § 262(*l*)(4) or as described in 42 U.S.C. § 262(*l*)(5).

165. Immunex/AML are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '631 patent by marketing, offering to sell, or selling within the United States Defendants' etanercept biosimilar product for treatment of psoriasis and/or psoriatic arthritis before the expiration of the '631 patent.

166. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Defendants from making, importing into, and selling within the United States Defendants' etanercept biosimilar product before the expiration of the '631 patent.

167. Defendants' marketing, offer for sale, or sale within the United States of Defendants' etanercept biosimilar product for treating psoriasis and/or psoriatic arthritis before the expiration of the '631 patent will cause Immunex/AML injury, entitling them to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Roche (with respect to the '182 and '522 patents) and Immunex/AML (with respect to all patents-in-suit) respectfully request that this Court enter judgment in their favor against Defendants and grant the following relief:

A. A judgment that Defendants have infringed one or more claims of the '182 patent under 35 U.S.C. § 271(e)(2)(C), by submitting to the FDA Defendants' aBLA to obtain approval of Defendants' etanercept biosimilar product under the PHSA to engage in the commercial manufacture, use, or sale of Defendants' etanercept biosimilar product before the expiration of the '182 patent;

B. A judgment that Defendants have infringed or will infringe one or more claims of the '182 patent by engaging in the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' etanercept biosimilar product before the expiration of the '182 patent;

C. A judgment that Defendants have infringed one or more claims of the '522 patent under 35 U.S.C. § 271(e)(2)(C), by submitting to the FDA Defendants' aBLA to obtain approval of Defendants' etanercept biosimilar product under the PHSA to engage in the commercial manufacture, use, or sale of Defendants' etanercept biosimilar product before the expiration of the '522 patent;

D. A judgment that Defendants have infringed or will infringe one or more claims of the '522 patent by engaging in the manufacture, use, offer for sale, or sale within the United

States, or importation into the United States, of Defendants' etanercept biosimilar product before the expiration of the '522 patent;

E. A judgment that Defendants have infringed one or more claims of the '225 patent under 35 U.S.C. § 271(e)(2)(C), by submitting to the FDA Defendants' aBLA to obtain approval of the Sandoz etanercept biosimilar product under the PHSA to engage in the commercial manufacture, use, or sale of Defendants' etanercept biosimilar product before the expiration of the '225 patent;

F. A judgment that Defendants have infringed, will infringe, or will induce infringement of one or more claims of the '225 patent by engaging in the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' etanercept biosimilar product before the expiration of the '225 patent;

G. A judgment that Defendants have infringed one or more claims of the '605 patent under 35 U.S.C. § 271(e)(2)(C), by submitting to the FDA Defendants' aBLA to obtain approval of Defendants' etanercept biosimilar product under the PHSA to engage in the commercial manufacture, use, or sale of Defendants' etanercept biosimilar product before the expiration of the '605 patent;

H. A judgment that Defendants have infringed, will infringe, or will induce infringement of one or more claims of the '605 patent by engaging in the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' etanercept biosimilar product before the expiration of the '605 patent;

I. A judgment that Defendants have infringed one or more claims of the '631 patent under 35 U.S.C. § 271(e)(2)(C), by submitting to the FDA Defendants' aBLA to obtain approval of Defendants' etanercept biosimilar product under the PHSA to engage in the commercial

manufacture, use, or sale of Defendants' etanercept biosimilar product before the expiration of the '631 patent;

J. A judgment that Defendants have infringed, will infringe, or will induce infringement of one or more claims of the '631 patent by engaging in the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' etanercept biosimilar product before the expiration of the '631 patent;

K. A judgment compelling Defendants to pay to Immunex/AML and Roche damages or other monetary relief adequate to compensate for Defendants' infringement, in accordance with 35 U.S.C. § 271(e)(4)(C) and § 284;

L. An injunction against future infringement and future inducement of infringement by Defendants, as well as all officers, employees, agents, representatives, affiliates, assignees, successors, and affiliates of Defendants, and all persons acting on behalf of or at the direction of, or in concert with Defendants, until the date of expiration of the last of the patents-in-suit;

M. A declaration that this is an exceptional case and awarding to Immunex/AML and Roche their attorneys' fees and costs pursuant to 35 U.S.C. § 285; and

N. Such other relief as this Court may deem just and proper.

DEMAND FOR A JURY TRIAL

Immunex/AML and Roche hereby demand a jury trial on all issues so triable.

Dated: February 26, 2016

Respectfully submitted,
Plaintiffs, by counsel:

s/ Liza M. Walsh

Liza M. Walsh
Christine I. Gannon
Eleonore Ofosu-Antwi
CONNELL FOLEY LLP

s/ David De Lorenzi

David De Lorenzi
Charles H. Chevalier
GIBBONS P.C.
One Gateway Center

One Newark Center
1085 Raymond Boulevard, 19th Floor
Newark, New Jersey 07102
(973) 757-1100

OF COUNSEL:

David T. Pritikin (dpritikin@sidley.com)
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, Illinois 60603
(312) 853-7000

Jeffrey P. Kushan (jkushan@sidley.com)
James A. High Jr. (jhigh@sidley.com)
SIDLEY AUSTIN LLP
1501 K Street N.W.
Washington, D.C. 20005
(202) 736-8700

M. Patricia Thayer (pthayer@sidley.com)
Vernon M. Winters (vwinters@sidley.com)
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, California 94104
(415) 772-1200

Samuel N. Tiu (stiu@sidley.com)
SIDLEY AUSTIN LLP
555 West Fifth Street
Los Angeles, California 90013
(213) 896-6000

Jill J. Schmidt (jschmidt@sidley.com)
SIDLEY AUSTIN LLP
1001 Page Mill Road, Building 1
Palo Alto, California 94304
(650) 565-7050

Attorneys for Immunex Corporation and Amgen Manufacturing, Limited

Newark, New Jersey 07102-5310
(973) 596-4500

OF COUNSEL:

David I. Berl (DBerl@wc.com)
Thomas S. Fletcher (TFletcher@wc.com)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, D.C. 20005
(202) 434-5000

Attorneys for Hoffmann-La Roche Inc.

RULE 11.2 CERTIFICATION

U.S. Patent No. 8,163,522 is the subject of a pending petition for *inter partes* review before the Patent Trial and Appeal Board of the United States Patent and Trademark Office docketed as *Coalition for Affordable Drugs V LLC et al. v. Hoffmann-La Roche Inc. et al.*, IPR2015-01792.

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: February 26, 2016

Respectfully submitted,
Plaintiffs, by counsel:

s/ Liza M. Walsh

Liza M. Walsh
Christine I. Gannon
Eleonore Ofosu-Antwi
CONNELL FOLEY LLP
One Newark Center
1085 Raymond Boulevard, 19th Floor
Newark, New Jersey 07102
(973) 757-1100

OF COUNSEL:

David T. Pritikin (dpritikin@sidley.com)
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, Illinois 60603
(312) 853-7000

Attorneys for Immunex Corporation and Amgen Manufacturing, Limited

s/ David De Lorenzi

David De Lorenzi
Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4500

OF COUNSEL:

David I. Berl (DBerl@wc.com)
Thomas S. Fletcher (TFletcher@wc.com)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, D.C. 20005
(202) 434-5000

Attorneys for Hoffmann-La Roche Inc.

RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: February 26, 2016

Respectfully submitted,
Plaintiffs, by counsel:

s/ Liza M. Walsh

Liza M. Walsh
Christine I. Gannon
Eleonore Ofosu-Antwi
CONNELL FOLEY LLP
One Newark Center
1085 Raymond Boulevard, 19th Floor
Newark, New Jersey 07102
(973) 757-1100

OF COUNSEL:

David T. Pritikin (dpritikin@sidley.com)
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, Illinois 60603
(312) 853-7000

Attorneys for Immunex Corporation and Amgen Manufacturing, Limited

s/ David De Lorenzi

David De Lorenzi
Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, NJ 07102-5310
(973) 596-4500

OF COUNSEL

David I. Berl (DBerl@wc.com)
Thomas S. Fletcher (TFletcher@wc.com)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, D.C. 20005
(202) 434-5000

Attorneys for Hoffmann-La Roche Inc.